K030072

APR 1 0 2003

F. 510(k) Summary

Applicant:	Stick Tech Ltd, PO Box 114, 20521 Turku, Finland Tel: +358-2-4808 2558 Fax: +358-2-241 0032
Contact Person:	Ilkka Kangasniemi, Ph.D.
U.S. Agent to respond to FDA requests:	William M. Troetel, Ph.D. 80 Parkway West Mount Vernon, NY 10552 Tel: (914) 664-1640 Fax: (914) 667-3993 wtroetel@westnet.com
Date Prepared:	December 17, 2002
Device Trade Name:	everStick™ PERIO
Device Common Name:	Glass fiber periodontal splint
Device Classificaton Name:	Denture relining, repairing, or rebasing resin (21 CFR §872.3760)

Description of Device:

everStick™ PERIO is a semi-manufactured product made of glass fibers and polymer/resin matrix. The glass fiber in everStick™ PERIO is unidirectional which increases the strength and stiffness of the final product perpendicular to the direction of the fibers.

Intended Use: For periodontal splinting

everStick™ PERIO is substantially equivalent to everStick™, approved under 510(k) number K011788 dated November 7, 2001.

The composition of everStick™ PERIO is equal with its predicate device, everStick™. Only the ratio of glass fibers and polymer matrices are slightly different.

By comparing the ingredients of everStick PERIO to the existing data available from dental polymerizable material, it can be stated that everStick PERIO does not expose the dentist nor the patient to unacceptable risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2003

Stick Tech Limited
C/O Dr. William Troetel
William M. Troetel, LLC
80 Parkway West
Mount Vernon, New York 10552

Re: K030072
Trade/Device Name: everStick™ PERIO
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: 76 EBI
Dated: April 4, 2003
Received: April 7, 2003

Dear Dr. Troetel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. Indications for Use Statement

510(k) Number (if known): K030072

Device Name: everStick™ PERIO

Indications for Use:

- For periodontal splinting.

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(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030072

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use __
(Per 21 CFR 801.109)

(Optional Format 1-2-96)